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UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

ILLUMINA, INC., and ILLUMINA CAMBRIDGE LTD., Plaintiffs, v. COMPLETE GENOMICS, INC., Defendant.	Case No. 3:12-cv-01465-BEN-BGS **DEFENDANT COMPLETE GENOMICS, INC.'S OPENING CLAIM CONSTRUCTION BRIEF** Date: July 11, 2013 Time: 9:00 A.M. Judge: Hon. Roger T. Benitez Place: 4B **REDACTED**

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CITATION CONVENTIONS

The following citation conventions are used in this brief:

- CGI = Complete Genomics, Inc.
- Illumina = Illumina, Inc.
- '930 patent = U.S. Patent No. 8,192,930
- XX:YY = column number:line number(s) of referenced patent
- Ex. = Exhibit
- All Exhibits refer to the exhibits attached to the Declaration of Marisa Williams In Support Of Defendant Complete Genomics, Inc.'s Opening Claim Construction Brief
- Emphasis added unless noted as part of the original
- Objections have been removed from cited deposition testimony

I. INTRODUCTION

CGI submits this claim construction brief to address the disputed terms of Claim 1 of the '930 patent. Pursuant to the claim construction principles set forth by the Federal Circuit, CGI proposes constructions firmly rooted in the intrinsic record. Illumina, by contrast, manufactures constructions to support its infringement case.

II. FACTUAL AND TECHNICAL BACKGROUND

A. The Instant Lawsuit

CGI is a life sciences company that provides sequenced human genomic data to researchers. CGI's competitor, Illumina, filed this lawsuit on June 15, 2012, ten days after CGI announced a restructuring program to stem cash consumption and a plan to search for a strategic solution to CGI's deteriorating financial condition.[1]

The '930 patent contains one independent claim (Claim 1) and twenty-five dependent claims (Claims 2-26). Illumina asserts only independent Claim 1 against CGI. The '930 patent teaches a method for pairwise sequencing of a double-stranded polynucleotide. The constructions of "in the same target double stranded polynucleotide" and "reading from a [first/second] primer" are the most significant terms in this dispute. Because CGI neither (1) uses a double-stranded polynucleotide in its sequencing assay, nor (2) sequences by successive incorporation of nucleotides into a growing polynucleotide chain, CGI does not infringe Claim 1. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[i]t is routine case management to require litigants to identify the aspects of their case that are material to the [claim construction] dispute"); Patent L.R. 4.2(a).[2]

[1] Previously, Illumina filed a lawsuit against CGI on August 3, 2010, two business days after CGI announced plans to seek $86 million in additional financing through an initial public offering. *See Illumina, Inc. and Solexa, Inc. v. Complete Genomics, Inc.*, Case No. 10-cv-05542 (EDL) (N.D. Cal.).

[2] No matter which construction the Court adopts, CGI will prevail in this litigation. If the Court adopts CGI's constructions, CGI does not infringe because it neither

(continued...)

B. DNA Basics

1. DNA Structure

DNA is a double-stranded molecule with two complementary chains running in opposite directions in the form of a double helix. Ex. C. Each strand of DNA is a chain of molecules ("nucleotides") with three parts: (1) a phosphate, (2) a sugar, and (3) one of four possible bases. *Id.* The phosphate and sugar structure of each regular nucleotide is constant, forming the "backbone" of the DNA strands—*i.e.*, the two opposing "legs" of the DNA ladder. *Id.* The structural variance occurs in the "rungs" of the DNA ladder—*i.e.*, the four different bases: adenine ("A"), cytosine ("C"), guanine ("G"), and thymine ("T")—which form base-pairs. *Id.*

The formation of base-pairs between bases on the two opposite strands causes the two strands to coil around each other into the double-helix structure described by Watson and Crick in 1953. Base A binds only to base T (and vice versa) while C binds only to G (and vice versa). *Id.* Complementary base pairing (*i.e.*, A/T and G/C base pairing between strands) makes DNA suitable for carrying genetic information, as one strand of DNA can act as a "template" for direct synthesis of a complementary strand and copy and pass on the "genetic code" to the next generation of cells. This template can be thought of as a photographic negative for the strand to be created, as the newly synthesized strand is not a duplicate of the template but rather its complementary sequence.

When two single strands of DNA containing complementary base sequences come together, specific pairing of bases takes place between the complementary

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uses a target double-stranded polynucleotide immobilized at both 5' ends nor sequences by successive incorporation of nucleotides into a polynucleotide chain. If the Court adopts Illumina's constructions, Claim 1 is invalid over the prior art, including Shendure, *et al.*, *Accurate Multiplex Polony Sequencing of an Evolved Bacterial Genome*, 309 Science 1728-1732 (2005) (Ex. B), and related work from the laboratory of Dr. George Church.

strands, forming a double-stranded DNA structure. This process is referred to as "hybridization." Ex. D. The double-stranded product may be called a "duplex." *Id.* Conversely, when a duplex separates into two single strands of DNA, this process is called "denaturation." *Id.* Both processes relate to temperature: rising temperatures facilitate denaturation while falling temperatures facilitate hybridization. *Id.*

A single strand of nucleotides has a direction to its structure that is established by its chemical makeup. Ex. E. This is denoted by names given to their ends: 5' ("5 prime") and 3' ("3 prime"), respectively. Ex. F. When two complementary strands hybridize, one strand is in the reverse orientation of the other strand (*i.e.*, the "top" strand runs 5' to 3'; the "bottom" strand runs 3' to 5'). *Id.*

2. Sequencing

After Watson and Crick discovered the double helical structure of DNA, scientists devised methods for ascertaining the identity and order of bases in DNA. In 1977, Dr. Sanger created a method for determining the nucleotide sequence in a DNA strand. In 1990, the Human Genome Project ("HGP") formed to sequence the human genome and completed a draft in 2003. The HGP primarily used an automated version of Sanger sequencing, but also led to investments to create alternative techniques to Sanger sequencing.

Many of the current "next-generation" (*i.e.*, post-automated Sanger) sequencing methods involve the same basic process, sometimes called "sequencing-by-synthesis." Sequencing-by-synthesis determines the sequence of a template polynucleotide. Ex. G (A-H). Part of the template has a known sequence and part may have an unknown sequence. *Id.* (A). First, a primer (a short stretch of nucleotides) hybridizes to a known complementary portion of the template.[3] *Id.* (B).

[3] If the template polynucleotide is present with both strands hybridized together, then the strands must be denatured to pull them apart before sequencing; otherwise, the primer could not squeeze in to hybridize to an individual strand.

Second, after the primer hybridizes, a mix of four nucleotides (A, T, G, C) along with an enzyme is introduced. *Id.* (C). Each nucleotide contains a "terminator" that ensures only one nucleotide incorporates at a time. Each nucleotide may also contain a label, typically a fluorescent tag attached to its end, to enable detection of nucleotide incorporation. Third, the enzyme, typically polymerase, adds a single complementary nucleotide to the 3' end of the primer. *Id.* (D). This nucleotide is complementary to the first nucleotide on the template after the primer. Notably, polymerase incorporates nucleotides in only one direction—from the 5' end to the 3' end of a strand. It never moves in the 3' to 5' direction. Fourth, once a nucleotide is incorporated into the primer, the other nucleotides are washed away. *Id.* (E). Fifth, a picture is taken of the fluorescent label. *Id.* (F). Each nucleotide may have a different color label—for example, the A nucleotide has a red label, the G nucleotide has a blue label, and so forth. If a red label is detected, it indicates that the A nucleotide was incorporated, and therefore, its complement, T, is located at that position on the template. Sixth, after detection of the first nucleotide incorporation, a "cleavage mix" is introduced that removes both the label and the terminator that prevents further incorporation. *Id.* (G). After the cleavage step, the process can be repeated in a new cycle. *Id.* (H). The next nucleotide incorporates into the nucleotide added in the previous cycle, and so on. With each cycle of nucleotide incorporation, the chain of nucleotides grows longer. After twenty-five cycles, for example, the primer will have a chain of twenty-five nucleotides added to its 3' end.

3. Amplification

Detecting labels from a single molecule can be difficult. Making thousands of copies of the molecule through a process called "amplification" eases detection. Measuring the signal (the color generated by the label) created by thousands of copies of the same DNA sequence in parallel sequencing reactions permits easier and more reliable detection. Running the reaction on thousands of copies also provides

quality control, as the predominant signal will be the correct signal and the outliers will be ignored or removed as background signal.

There are many ways to amplify DNA molecules. One way, called "cluster" or "bridge" amplification, creates clusters of DNA molecules immobilized (*i.e.*, attached) to a solid support. The patent teaches cluster amplification and describes two primary cluster amplification methods, both incorporated by reference: WO 98/44151 and WO 00/18957. 3:4-9; 5:59-63; 22:37-42; 25:29-60; 26:47-54; *see also* 27:1-3. A solid support (*e.g.*, a glass bead or a slide called a flow cell) anchors the amplified DNA molecules so that they remain in one place. Ex. H.

First, the cluster amplification process begins with a template strand attached to solid support at its 5' end, surrounded by thousands of short pieces of DNA attached to the solid support (called "grafted primers") to create a "lawn." The template strand is attached to the solid support through a grafted primer, which becomes the 5' end of the strand.[4] The 3' end of the template remains free. Both ends have known sequences. Ex. I (A).

Second, the 3' end of the template has a known sequence complementary to one of the many grafted primers in the "lawn." Because of this complementarity, when the temperature is lowered to facilitate hybridization, the template strand will "bend down" to hybridize to the grafted primer, thus forming a "bridge." *Id.* (B).

Third, once the template and grafted primer are in a bridge structure, nucleotides and polymerase are added to generate a new strand from the grafted primer that is complementary to the template strand. This process transforms the single-stranded bridge into a double-stranded bridge. The double-stranded bridge

[4] In WO 98/44151, the primer is attached to solid support first, then joined with the template. *See* Ex. L; 25:40-60. In WO 00/18957, the primer and template are joined first, then attached to solid support. *See* Ex. M; 25:29-39.

has two 5' ends (one from each strand) and two 3' ends (one from each strand). The 5' ends are attached to solid support while the 3' ends remain free. *Id.* (C).

Fourth, the temperature is raised to facilitate denaturation of the double-stranded bridge structure. The two strands come apart from the bridge structure and stand up, with their 5' ends remaining attached to the solid support and their 3' ends remaining free. Thus, the first cycle of cluster amplification has transformed a single template strand into two complementary template strands. *Id.* (D).

Fifth, the two template strands initiate the next cycle of amplification. *Id.* (E). While the first cycle of cluster amplification produces two strands, the second cycle produces four strands, the third cycle produces eight strands, and so on. *Id.* (F). This exponential amplification results in dense clusters of double-stranded DNA. Each cluster contains copies of the original strand and its complement. Ex. J. Depending on the number of amplification cycles, one cluster could have thousands of copies of a strand and its complement, each immobilized to solid support at its 5' end.

C. Pairwise Sequencing Was "Known In The Art" Well Before The '930 Patent

1. History Of Pairwise Sequencing

Pairwise sequencing is an old method. In 1981, Hong published an early description of pairwise sequencing in which two regions of a double-stranded polynucleotide were sequenced using a first and second primer.[5] In the following years, scientists expanded on early pairwise sequencing methods, including by using two primers to read the ends of double-stranded polynucleotides to assemble the first genome from a self-replicating organism.[6]

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[5] G.F. Hong, *A method for sequencing single-stranded cloned DNA in both directions*, 1 Bioscience Reports 243-252 (1981).

[6] *See, e.g.*, Robert D. Fleischmann, *et al.*, *Whole-Genome Random Sequencing and Assembly of Haemophilus influenzae Rd*, 269 Science 496-512 (1995).

These developments paved the way for efforts to sequence the human genome, a highly complex genome comprised of roughly three billion base pairs. The main obstacle to sequencing was the limit on how many consecutive bases could be read at once (*e.g.*, Sanger sequencing reads 100-1000 base pairs) and how to reassemble such "short reads" into one three billion base pair sequence. One solution was shotgun sequencing, where DNA is randomly broken into fragments that are sequenced and then reassembled to produce the overall sequence. Multiple copies of DNA are fragmented, so each portion of DNA is represented multiple times in different overlapping fragment frames. Overlapping end-sequences are pieced together to assemble the larger stretch of DNA. Because of these benefits, both the HGP and the parallel project at Celera Genomics produced finished sequences of the human genome using pairwise sequencing.[7]

2. The Patent Recognized Prior Pairwise Sequencing Advances

The '930 patent acknowledges that pairwise sequencing was "generally known in the art of molecular biology." 2:1-3. It recognized that pairwise sequencing had allowed scientists to obtain "two 'reads' of sequence from two places on a single polynucleotide duplex"; thus, rather than sequencing two independent templates, one could sequence two stretches of one double-stranded template. 2:5-13. Knowing that the two reads are "linked or paired in the genome" had aided previous efforts to assemble whole genome sequences into a larger ordered sequence. 2:13-21. Thus, the alleged "invention" in the '930 patent must be something more than the mere concept of pairwise sequencing.

[7] E.S. Lander, *et al.*, *Initial sequencing and analysis of the human genome*, 409 Nature 860, 860-921 (2001); J. Craig Venter, *The Sequence of the Human Genome*, 291 Science 1304-1351 (2001).

D. '930 Patent

1. Specification

The Summary of the Invention establishes that the invention is a method for pairwise sequencing, which refers to "a pair of reads obtained by sequencing two distinct regions, either on the same strand or the complementary strand of a target polynucleotide duplex." 3:19-63. "***According to the invention***," the method comprises the following steps to "achieve[] pairwise sequencing" of two regions of the double-stranded polynucleotide: (1) providing a double-stranded template polynucleotide with each strand linked to solid support at its 5' end; (2) denaturing the double-stranded template polynucleotide; (3) hybridizing a first sequencing primer to one of the template strands; (4) performing a first sequencing reaction by sequential addition of nucleotides to the first sequencing primer; (5) removing the first extended sequencing primer; (6) hybridizing a second sequencing primer to one of the template strands; and (7) performing a second sequencing reaction by sequential addition of nucleotides to the second sequencing primer. *Id.*

The patent teaches cluster amplification to generate the double-stranded polynucleotide templates for sequencing. Indeed, the "***starting point for the method of the invention***" is a cluster of polynucleotide duplexes attached to solid support. 5:59-62. Each duplex is "formed from complementary first and second template strands which are linked to the solid support at or near to their 5' ends." 5:63-6:2.

The Summary of the Invention describes three embodiments. Each begins with a double-stranded polynucleotide attached to solid support at the 5' ends. 3:32-4:24. In the first embodiment, the two strands are denatured to allow primers with different sequences to hybridize to locations on the individual strands and initiate each of the sequencing runs. Ex. K; 3:64-4:2. In the second embodiment, the double-stranded polynucleotide contains a region of known sequence which contains a site for cleaving (*i.e.*, cutting) between two regions of unknown sequence. Ex. K;

3:3-15. When the double-stranded polynucleotide is in bridge form, it can be cut at the cleavage site, resulting in two shorter double-stranded polynucleotides. *Id.* Denaturation removes the unbound strand from each short polynucleotide, leaving two template strands, each attached at the 5' end. *Id.* Each strand is separately sequenced to generate two reads. *Id.* In the third embodiment, the double-stranded polynucleotide contains a region of known sequence between two regions of unknown sequence (like the second embodiment). Ex. K; 3:16-24. One strand may be cleaved from the solid support through a process called "linearization" and removed by denaturation.[8] Removing one strand eliminates "competition" issues that can interfere with hybridization of the first sequencing primer. For example, the template strand can hybridize to either its complement or the short sequencing primer. Thus, the sequencing primer must compete with the complementary strand during hybridization. Cutting one strand reduces this competition.[9]

2. Prosecution History

The original draft of the application for the '930 patent, which claimed priority to an international application, did not contain the current independent Claim 1. Ex. N. Rather, current dependent Claim 2 was the only independent claim. *Id.*

On the day prosecution began in the USPTO, Illumina filed a preliminary amendment.[10] *Id.* The primary change was the addition of new Claim 27 to the patent. *Id.* Claim 27 ultimately became the current independent Claim 1, and the

[8] The third embodiment does not require linearization; alternatively, the cleaving step can be skipped and both strands may be sequenced. *See* 13:15-19.

[9] The second embodiment also reduces this competition issue. By cutting the bridge structure in half, the remaining shorter strands are no longer complementary to each other, and therefore, are not inclined to re-hybridize to each other and displace the sequencing primer. *See* 9:42-50.

[10] A preliminary amendment enables the patentee to amend the claims or specification before the USPTO begins review. 37 C.F.R. § 1.115.

original Claim 1 became the current dependent Claim 2. *Id.* The specification was not substantively changed. *Id.*

In submitting new Claim 27 to the USPTO, Illumina stated the following:

> New claim 27 [now Claim 1] is also submitted herewith. Support for new claim 27 is found throughout the specification and in the original claims. More specifically, support for new claim 27 is found, *inter alia*, in *original claim 1* [now Claim 2]. *No issue of new matter is hereby introduced*.

Id. at 8. Therefore, the only specific source of support for new Claim 1 was in Claim 2. Nothing was added to provide further support for new Claim 1. Indeed, Illumina represented that "[n]o issue of new matter is hereby introduced," as applicants cannot add information beyond the subject matter originally filed. *Id.*

The Examiner later rejected new Claim 1 because a prior art reference, Weimann, taught the simultaneous sequencing of two template regions. Ex. O at 6. Illumina amended new Claim 1 to add the phrase "followed by" to clarify that the sequencing reactions are not simultaneous but sequential, as the first primer is removed before the second primer is hybridized in a different location. Ex. R at 2-3; *see also* Exs. P-S. Only after this amendment did the Examiner agree to allow new Claim 1. Ex. T at 2-3.

III. THE LAW OF CLAIM CONSTRUCTION

Construction of patent claims is a question of law to be decided by the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 371-73 (1996). Claim terms are "'generally given their ordinary and customary meaning'" which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*). "It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp. v.*

Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citation omitted). Such intrinsic evidence is the most significant source of claim meaning. *Id.*

The specification provides the context for the claim. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313. The claims "must be read in view of the specification, of which they are a part." *Id.* at 1315. Indeed, the specification "'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* "'[T]he best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history.'" *Id.* (internal quotation marks omitted). The prosecution history also informs claim construction. *Id.* at 1317 ("Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent."). If ambiguities in the claim terms remain after examining the intrinsic record, courts may consider extrinsic evidence, including inventor testimony. *Id.*; *Vitronics*, 90 F.3d at 1584.

IV. CGI'S PROPOSED CLAIM CONSTRUCTIONS

A. Claim 1

The sole asserted claim of the '930 patent (Claim 1) reads as follows:

> A method for pairwise sequencing of first and second regions of a double stranded polynucleotide wherein said first and second regions are in the same target double stranded polynucleotide, the method comprising hybridising and reading from a first primer, removing the first primer followed by hybridising and reading from a second primer at a different location in the same target double stranded polynucleotide.

1. "in the same target double stranded polynucleotide"

CGI's Proposed Construction	Illumina's Proposed Construction
in the template polynucleotide duplex formed from complementary first and second template strands which are linked to the solid support at or near their 5' ends	in the same strand or complementary strands derived from the original polynucleotide duplex from which sequencing information is desired

The parties dispute whether this term refers to the duplex attached to the solid support for sequencing or the generic starting material. The patent contemplates that the invention employs a *double-stranded* polynucleotide—meaning, a strand *and* its complement are attached to the solid support and available for sequencing. CGI's construction accounts for this requirement. But Illumina disregards it, and instead, offers a construction divorced from the teachings of the patent. In an effort to expand the scope of Claim 1, it seeks a strained reading of this term such that Claim 1 would cover the sequencing of *any* material that has *ever* been in double-stranded form, *i.e.*, ***all*** genomic DNA, regardless of how the target material is prepared for sequencing. This construction cannot be correct in view of the repeated emphasis on the attachment of double-stranded polynucleotides to solid support for sequencing, as well as the extensive history of pairwise sequencing on genomic DNA. CGI's construction is consistent with the specification, purpose, and purported novelty of the invention, and therefore, should be adopted.

a. Both Strands In The Same Target Double-Stranded Polynucleotide Are Attached At Or Near The 5' Ends.

i. Attachment Of Both Strands Is A Necessary Feature Of The Invention.

The invention requires that the target double-stranded polynucleotide contains two strands attached at their 5' ends. Not only does the patent underscore throughout the specification the necessity of attaching both strands, it even describes attachment as a novel aspect of the invention taught for the first time by the patent's inventors.

Critically, the Summary of the Invention states that "***[a]ccording to the invention***," the first step of the sequencing method is:

> providing a solid support having immobilised thereon a plurality of double stranded template polynucleotides *each formed from complementary first and second template strands linked to the solid support at their 5' ends*.

3:32; 3:37-40. CGI's construction adopts this definitional language, which describes the entire invention. Statements in the Summary of the Invention, particularly language such as "according to the invention," describe the invention as a whole. *Gaus v. Conair Corp.*, 363 F.3d 1284, 1290 (Fed. Cir. 2004) ("according to the invention" statement referred to the entire invention); *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004) (Summary of the Invention tends to describe the entire invention); *Morvil Tech., LLC v. Medtronic Ablation Frontiers, LLC*, No. 10-cv-2088, 2012 WL 3277272, at *16 (S.D. Cal. Aug. 10, 2012) (Benitez, J.) (use of the "present invention" in the Summary of the Invention was "strong evidence" that the passage described the entire invention). Therefore, attaching both strands of the target double-stranded polynucleotide is not merely the feature of a single embodiment, but a requirement of the entire invention.

This requirement is reiterated throughout the remainder of the specification. For example, CGI's construction tracks the language of the Detailed Description of the Invention: "***[t]he starting point for the method of the invention*** is the provision of a plurality of template polynucleotide duplexes immobilised on a solid support" wherein each duplex is "*formed from complementary first and second template strands which are linked to the solid support at or near to their 5' ends*." 5:59-62; 5:65-6:1; *see also* 8:58-9:2.

Moreover, the patent considered the attachment of both strands to be a novel aspect of the invention. It admits that ditags (paired-end tags) were known in the art, but asserts that the *amplification of ditags to generate a cluster of duplexes with both strands immobilized to solid support* was taught for the first time in the '930 patent:

> The amplification of single molecules of such ditags to produce a clustered array wherein both strands of each amplified duplex are immobilised, *as taught for the first time by the present inventors*, confers a significant advantage in that it is possible to simultaneously analyse a large number of ditags of different sequences on a single solid support.

See 10:54-60. Thus, the use of duplexes formed from complementary first and second template strands attached at their 5' ends is not only necessary to the entire invention but one of the purportedly novel aspects of the invention.

ii. Each Embodiment Begins With Both Strands Immobilized At Their 5' Ends.

Each embodiment necessarily begins with both strands attached to the solid support at their 5' ends. This is the "***starting point for the method of the invention***." 5:51-62. After this step, the sequencing method may diverge into one of three embodiments: (1) sequencing both strands (Ex. K; 3:64-4:2; Example 5); (2) sequencing both shorter strands after cutting the double-stranded polynucleotide at the cleavage site (Ex. K; 4:3-15; 9:42-50; Figure 8); or (3) sequencing two regions in one strand after cleaving the other strand (or, alternatively, skipping the cleavage step and sequencing both strands) (Ex. K; 4:16-24; 13:1-33; Examples 6-7). The common denominator, however, is the first step of providing a double-stranded polynucleotide with both strands attached to solid support at their 5' ends.

iii. Immobilization Of Both Strands Is The Product Of Cluster Amplification.

That all embodiments begin with their 5' ends attached to solid support is consistent with—and in fact, compelled by—the cluster amplification taught in the patent. The patent instructs that "[t]he starting point for the method of the invention is the provision of a plurality of template polynucleotide duplexes immobilised on a solid support in the form of amplified clusters as described in WO9844151 and

WO00018957, whose contents are incorporated herein by reference." 5:59-63. WO9844151 and WO00018957 both taught cluster amplification that would:

> allow amplification products to be immobilised on a solid support in order to form arrays comprised of clusters or "colonies" formed from a *plurality of identical immobilised polynucleotide strands and a plurality of identical immobilised complementary strands*.

3:4-9. Accordingly, cluster amplification necessarily produces double-stranded polynucleotides attached to solid support. *See id*; *see also* 5:59-6:2. These cluster amplification products are then used in the sequencing reactions.

iv. Immobilization Of Both Strands Is Driven By The Purpose Of The Invention.

The purpose of the invention likewise drives the attachment requirement, and is relevant to claim construction. *Tech. Patents LLC v. T-Mobile (UK) Ltd.*, 700 F.3d 482, 493-94 (Fed. Cir. 2012) (construing claim terms in view of the invention's purpose). The patent's objective is to obtain two reads from a duplex to achieve pairwise sequencing. 3:19-63. That both strands are attached to the solid support is crucial to the invention. Otherwise, the invention would not work. In between the first and second sequencing reactions, a denaturation step (by heat or chemical treatment) removes the first extended primer so that the second sequencing reaction can begin. 21:24-31. If the strands were not immobilized, denaturation would sweep away both the first extended primer *and* the strands. Because the second read must come from the same template (paired reads), the strands must survive denaturation and remain bound to solid support. 3:19-63. Therefore, immobilization is critical to the success of the invention.

b. The Inventor Testimony Supports CGI's Construction.

[redacted] *Voice Techs. Grp., Inc. v.*

VMC Sys., Inc., 164 F.3d 605, 615 (Fed. Cir. 1999) (inventor testimony is useful if the inventor does not change the claim meaning from when the patent was granted).

[redacted]

c. Illumina's Vague Construction Ignores The Specification In Favor Of Expanding The Scope Of Claim 1 Far Beyond The Patent's Disclosures.

Illumina cannot defend the breadth of its proposal. Its construction could capture any generic starting material that has at one time been double-stranded and "from which sequencing information is desired." This construction is flawed on multiple levels. First, Illumina's vague construction could capture an unjustifiably wide swath of sequencing. "[O]riginal polynucleotide duplex" could refer to any starting material that has ever been in double-stranded form, including DNA (which is naturally double-stranded) and even RNA (which originates as single-stranded but which the patent teaches can be converted into double-stranded (7:15-25))—no matter what kind of polynucleotide template was created and used in the actual sequencing reaction. In sum, Illumina's construction completely divorces the "double-stranded" limitation from the sequencing reaction at all. Nearly any pairwise sequencing of DNA, including numerous prior art sequencing methods, could infringe the patent under Illumina's construction. For example, obtaining paired reads from any strand ("same strand or complementary strands") of an

original DNA double-helix ("original polynucleotide duplex") could infringe. Such a broad construction is plainly unreasonable in view of the long history of pairwise sequencing of DNA outlined in Section II.C and the patent's acknowledgement that pairwise sequencing was known in the art. It is also strained in view of the patent's statement that immobilization of both strands (hence, the "double-stranded" polynucleotide) was novel and taught by the inventors for the first time. *See* 10:52-60. That the strands are attached is a central feature of the patent. Illumina's construction reads out this critical aspect of the invention.

While Illumina's use of the term "original polynucleotide duplex" in its proposed construction is vague, it actually lends further support to CGI's construction when viewed in the context of the intrinsic record. The phrase "original polynucleotide duplex" appears twice in the patent, each time referring to the cluster amplification product immobilized on the solid support, consistent with CGI's construction. *See* 3:64-67 ("both strands of the *original polynucleotide duplex* remain immobilised" in the first embodiment); 9:42-50 (referring to the cluster amplification product immobilized on solid support, before being cleaved into the two shorter strands that are sequenced in the second embodiment).

Second, to the extent Illumina argues that Claim 1 is significantly broader than Claim 2, this assertion is undermined by the prosecution history. Claim 1 was added at the beginning of prosecution, with specific support for the new claim found only in Claim 2. Ex. N at 8. Claim 2 expressly requires that the strands of the double-stranded polynucleotide are "linked to the solid support at their 5' ends." If Claim 1 did not share this limitation, Illumina would have identified other specific parts of the patent that supported this increased scope beyond the disclosures of Claim 2. But Illumina did not, and indeed, the Summary of the Invention confirms that immobilization is common to the entire invention. 3:32-40.

2. "reading from a [first/second] primer"

CGI's Proposed Construction	Illumina's Proposed Construction
the successive incorporation of nucleotides into a polynucleotide chain synthesized in the 5' to 3' direction from the [first/second] primer and the determination of the nature of the nucleotide after each incorporation	obtaining sequence information near where the [first/second] primer has hybridized

The parties dispute whether the patent discloses using a sequencing method of successive incorporation of nucleotides or whether any sequencing method at all can be used. CGI's proposal directly tracks the language of the specification and is faithful to the repeated advisement that sequencing proceeds by the successive incorporation of nucleotides. By contrast, Illumina's construction ignores these disclosures and would dramatically inflate the scope of Claim 1.

a. The Specification Teaches Successive Incorporation Of Nucleotides Into A Polynucleotide Chain.

The specification repeatedly states that sequencing proceeds by the successive incorporation of nucleotides into a polynucleotide chain. CGI's construction directly tracks the language of these passages.

First, the Summary of the Invention specifies that "***[a]ccording to the invention***," sequencing is performed by "*sequential addition of nucleotides* to the [first/second] sequencing primer." 3:47-51; 3:56-63. This statement characterizes the entire invention. *See Gaus*, 363 F.3d at 1290; *C.R. Bard*, 388 F.3d at 864; *Morvil*, 2012 WL 3277272, at *16.

Second, the description of the "***method of the invention***" reiterates that sequencing is carried out by the successive incorporation of nucleotides into a growing polynucleotide chain. *See* 20:20-21. CGI's construction adopts the language of this section: "a sequencing reaction proceeds via *successive incorporation of nucleotides* to the [first/second] sequencing primer." 21:13-18; *see*

also 21:24-31. The specification further notes that the successive incorporation of nucleotides results in a *polynucleotide chain*. Sequencing can be carried out by any "sequencing-by-synthesis" method, where "nucleotides are added *successively*" resulting in "*synthesis of a polynucleotide chain* in the 5' to 3' direction." 21:32-38. One example refers to "the *growing polynucleotide chain*" complementary to the template and "the nature of *the base incorporated* into the *growing chain*." 21:43-51. The specification also explains that:

> The methods of the invention are not limited to use of the sequencing method outlined above, but can be used in conjunction with essentially any sequencing methodology *which relies on successive incorporation of nucleotides into a polynucleotide chain*.

22:9-13. Therefore, at a minimum, "reading from a [first/second] primer" requires the successive incorporation of nucleotides into a polynucleotide chain.

The figures and examples further demonstrate the successive incorporation of nucleotides into the sequencing primers. Figure 1 depicts twenty-five cycles of "SBS," that is, the successive incorporation of twenty-five nucleotides added to the primers. Figure 1; 4:28-38 ("single base sequencing SBS through 25 cycles"). The examples also teach repeated cycles of sequencing. Example 5 ("[c]ycles of sequencing enzymology" and "sequencing run" from the second primer); Example 6 ("sequencing run" from the first primer); Example 7 ("sequencing cycles").

The patent does not depict any sequencing method that does not rely on the successive incorporation of nucleotides. This is consistent with the instruction that, "***according to the invention***," sequencing proceeds by the sequential addition of nucleotides, and the advisement that sequencing can be performed by any method of "successive incorporation of nucleotides into a polynucleotide chain." 3:47-51; 3:56-63; 22:9-13. Therefore, "reading from a [first/second] primer" requires the successive incorporation of nucleotides into a polynucleotide chain.

b. The Specification Supports The Other Aspects Of CGI's Construction.

The specification directly supports the other elements of CGI's construction. CGI's construction tracks the language from these passages. First, the patent teaches sequencing in only one direction, from 5' to 3'. *See* 21:32-38 ("synthesis of a polynucleotide chain in the 5' to 3' direction"). This is the only explicit mention of sequencing directionality in the patent. Second, the invention of Claim 1 requires the determination of the nucleotide incorporated in each sequencing cycle. The Summary of the Invention requires that one "determine the sequence" (*i.e.*, the nature of each nucleotide) of the regions. *See* 3:47-51; 3:56-63. Indeed, the patent describes means of identification to determine "*the nature of the nucleotide added . . . after each addition*." *See* 21:36-38; *see also* 21:39-22:8 (determining the "nature of the base incorporated into the growing chain"; "discriminat[ing] between the bases at each incorporation step"; "detection of the incorporation of the nucleotide into the DNA sequence").

c. Illumina's Vague Construction Impermissibly Broadens The Scope Of Claim 1.

Illumina's construction would dramatically enlarge the scope of Claim 1 to an impermissible extent. Indeed, under Illumina's proposal, any and every means of "obtaining sequencing information" would be covered by Claim 1. There is not a broader construction that Illumina could seek.

First, the construction is found nowhere in the specification. The phrase "obtain[ing] sequence information near where the [first/second] primer has hybridized" does not appear in the patent. The word "near" appears only twice in the patent, both times in a context unrelated to reading. CGI's construction is preferable because it directly tracks the language of the specification. *See Gen-Probe Inc. v. Becton Dickinson*, No. 09-cv-2319, 2011 WL 7167137, at *4 (S.D. Cal. Nov. 22,

2011) (Benitez, J.) (adopting construction that "tracks language in the summary of the invention section" and rejecting construction that was "vague and ambiguous" and did not appear in the specification).

Second, Illumina's proposal ignores the instruction that "***[a]ccording to the invention***," sequencing is carried out via sequential addition of nucleotides. Not only is this point reiterated throughout the specification, but the patent explicitly sets an outer boundary on the sequencing methods used in the invention. It does not permit *any* means of "obtaining sequencing information." Quite the opposite, it states that sequencing may be carried out with "any sequencing methodology *which relies on successive incorporation of nucleotides into a polynucleotide chain*." 22:9-13. The Summary of the Invention confirms that all sequencing in the patent proceeds by successive incorporation of nucleotides. *See* 3:47-51; 3:56-63 ("According to the invention" sequencing reactions are performed by "sequential addition of nucleotides to the [first/second] sequencing primer"). Illumina's broad construction belies this boundary and finds no support in the patent.

Third, the prosecution history further undercuts Illumina's broad construction. When Claim 1 was added, Illumina represented that no new matter was introduced and the new claim found specific support only in Claim 2. Ex. N at 8. Claim 2 carries out sequencing reactions "using cycles of primer extension with a polymerase and labeled nucleotides." If Claim 1 was much broader, Illumina needed to identify other specific parts of the patent that supported this increased scope beyond Claim 2 or tell the USPTO that it was new, but Illumina did not do so.

d. Illumina's Broad Construction Injects More Ambiguity Into Claim 1.

Illumina's construction is impermissibly vague. Constructions that would only introduce further ambiguity into a claim are disfavored. *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003) (declining to adopt

construction that would prevent one of ordinary skill from knowing if variations on the invention would be within the claim scope). Illumina's proposal would require further constructions from the Court to determine what "obtaining sequence information near where the [first/second] primer has hybridized" even means.

This construction could capture scenarios plainly not contemplated by the patent. First, it fails to tie the act of reading bases to the actual first/second primer from which they are to be read. Nucleotides are added directly *into* the primer (or extended primer) to form a growing polynucleotide chain, not merely *near* the primer, and actually become part of the same molecule. Under Illumina's construction, after the first or second primer has hybridized to a location (even if it has long been removed), any reading occurring anywhere "near" the original location of the first/second primer would satisfy this claim element. To illustrate, one could hybridize a third or tenth or thirtieth primer "near" where the first/second primer hybridized, and read bases, and this would satisfy the claim element because it "obtain[ed] sequence information *near* where the [first/second] primer has hybridized." Second, the word "near" provides no guidance and only introduces confusion.[11] It is unclear if "near" means that sequence information is obtained from a location one base, one hundred bases, one thousand bases, etc., from where the first/second primer hybridized. In the context of human genomic DNA, which contains three billion base pairs and can be broken down into small fragments that still may span hundreds of bases, it is impossible to discern the boundary of "near." Illumina's proposal not only would hamper application of this construction in a non-infringement or invalidity analysis, but would make it impossible for an accused infringer to understand the claim and what methods would, in fact, infringe.

[11] In fact, "near" could be interpreted to mean a "short distance away" which could actually exclude from coverage the direct incorporation of a nucleotide adjacent to a primer, thus excluding the embodiments described in the patent.

3. "removing the first primer"

CGI's Proposed Construction	Illumina's Proposed Construction
heating or chemically denaturing from the surface the first sequencing primer when the first sequencing reaction is complete	"removing the first primer" need not be construed, or if construed, the Court should construe this phrase as having its plain and ordinary meaning

The parties dispute whether "removing the first primer" should be construed according to the teachings in the specification or given its plain meaning (a meaning which Illumina never states). Because CGI's proposal is rooted in the specification, and Illumina offered no actual construction, the Court should adopt CGI's proposal.

a. CGI's Construction Ties Directly To The Specification.

CGI's construction of "removing the first primer" has two components: (1) the means of removal; and (2) the timing of removal. First, the specification teaches two means for removing the first primer: heat or chemical denaturation. No other removal method is taught. CGI's construction tracks the language describing the removal means in the "method of the invention": the primer is "removed from the surface" either by "heating, or chemical denaturation." 21:24-26. The use of heat or chemical denaturation is reiterated throughout the specification. *See* 3:64-4:2 (removal step "may involve a thermal or chemical treatment"); 9:3-7 (removal means can be "heat" or a "chemical treatment with a denaturing solution"); Examples 5 & 6 (denaturation with chemical treatment).

Second, the removal step always occurs when the first sequencing reaction is complete. CGI's construction adopts the language from the description of removal in the "method of the invention": "*[w]hen the first sequencing reaction is complete*, the extended first sequencing primer is removed from the surface." 21:24-25. The remainder of the specification confirms this point. *See* 3:47-53 (step (d) teaches "performing a first sequencing reaction" while step (e) teaches "removing the first extended sequencing primer from step (d)"); 13:12-15 (first sequencing primer "can then be removed and a second sequencing primer introduced to allow a second

read"); 13:27-31 (first sequencing primer is "used as the primer for a sequencing reaction, after which it is removed from the template"). The figures and examples also depict this sequence of steps. *See* Fig. 1 (after the first sequencing run, "[s]trip extended primer with chip on the sequencing instrument"); Example 5 (denaturation with sodium hydroxide after first sequencing run); Example 6 ("After the first sequencing run, this process can be repeated to remove the first run and hybridise the second sequencing primer"); Example 7 ("hybridise a first sequencing primer to a linearised cluster, obtain a sequencing read, remove the first extended primer . . . .").

b. Illumina Failed To Propose Any Construction.

Illumina failed to propose any construction for this term, and instead, only asserted that "removing the first primer" should carry its plain and ordinary meaning (a meaning which Illumina fails to identify). But a patentee cannot avoid defining its own claim term by asserting only that its term has a plain meaning. *Liebel-Flarsheim Co. v. Medrad Inc.*, No. 1:04-cv-607, 2006 WL 335846, at *6 (S.D. Ohio Feb. 14, 2006) (patentee improperly failed to submit actual constructions based on asserted plain and ordinary meaning); *Ronald A. Smith & Assoc. v. Hutchinson Tech. Inc.*, No. 01-cv-3847, 2002 WL 34691122, at *1 (N.D. Cal. Aug. 16, 2002) (patentee improperly asserted plain meaning then refused to propose actual plain meaning).

Even if Illumina had proposed a construction, the Court must examine the term in the context of the specification and cannot automatically resort to a generic plain meaning. *See DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1324 (Fed. Cir. 2001) (refusing to look at the ordinary meaning of "frame" in a vacuum, but only in the context of the written description and prosecution history). The patent sets forth two means of removal (heat or chemical denaturation) at a specific point in the sequencing process (when the first sequencing reaction is complete). A construction divorced from these teachings and based solely on some undetermined meaning of "removing the first primer" is improper.

4. "first and second regions"

CGI's Proposed Construction	Illumina's Proposed Construction
two distinct portions of the target double-stranded polynucleotide for sequence determination. The first and second regions for sequence determination are either on the same strand, or on complementary strands, of the double-stranded polynucleotide template	two distinct and separate single-stranded portions

The parties dispute whether the "first and second regions": (1) must merely be distinct, or distinct *and* separate; and (2) must be located on either the same strand or complementary strands of the double-stranded polynucleotide template. While CGI's construction is firmly rooted in the specification, Illumina's construction rests on a single mention of the word "separate" in the Abstract and fails to incorporate the location of the regions in one or both strands of the template.

a. CGI's Construction Is Drawn Directly From Language In The Entire Specification.

CGI's construction of "first and second regions" contains two components: (1) the regions are distinct, but not necessarily separate, portions of the target double-stranded polynucleotide; and (2) the regions are either on the same strand or complementary strands of the target double-stranded polynucleotide.

First, CGI's construction is drawn directly from the Summary of the Invention. This section states that the object of the pairwise sequencing method is to obtain a pair of reads by "sequencing *two distinct regions*, either on the same strand or the complementary strand of a target polynucleotide duplex." 3:24-26. Defining the regions merely as "distinct," not "separate," in the Summary of the Invention indicates that the *invention as a whole* requires only distinct regions and does not

preclude overlapping regions.[12] *See Gaus*, 363 F.3d at 1290; *C.R. Bard*, 388 F.3d at 864; *Morvil Tech.*, 2012 WL 3277272, at *16.

The remainder of the specification only bolsters the statement in the Summary of the Invention. *See Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1345-1348 (Fed. Cir. 2001) (statement in the Summary of the Invention supported broader construction where rest of written description did not contradict that construction). The regions must only be distinct from each other, sequenced with different primers that hybridize to different locations. *See* 4:21-23 ("[t]he resultant single stranded polynucleotide, anchored via the 5'-end contains *two distinct regions* able to hybridise a sequencing primer"); 13:31-33 ("a second sequencing primer is hybridised and used for sequencing of a *different* region of the single stranded template"); *see also* 3:65-67; 4:37-38; 9:47-50 (two primers with different sequences used to generate each of the sequencing runs).

Second, CGI 's construction reflects that the first and second regions are always positioned on either the same strand or complementary strands of the template. CGI's construction adopts, verbatim, language from the specification that describes the "invention" as a whole: "[t]he first and second regions for sequence determination are either on the same strand, or complementary strands, of the double-stranded polynucleotide template." 5:51-58. The Summary of the Invention reiterates that the regions are "either on the same strand or the complementary strand of a target polynucleotide duplex." 3:24-26. The examples further demonstrate this fact. *See* Example 5 (regions on both strands); Example 6 (regions on same strand); Example 7 (regions on same strand).

[12] [redacted]

b. Illumina's Construction Is Not Consistent With The Specification.

Illumina's construction runs afoul of the specification in two ways: (1) it requires "separate" regions even though the specification requires only "distinct" regions; and (2) it ignores the fundamental requirement that the regions be on the same strand or complementary strands of the polynucleotide template.

First, Illumina's construction is not compelled by the specification. To support its proposal that the "first and second regions" must be both distinct and separate, Illumina relies on a single mention of "separate" regions in the Abstract. But a single statement in the Abstract that contradicts the entirety of the specification should not be viewed as a limitation on claim scope. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1121 (Fed. Cir. 2004) (Abstract set forth general information about the patent and did not "operate as a clear expression of manifest exclusion" in view of the specification). Illumina relies solely on the use of "separate" in the Abstract to support its construction in the face of contradictory evidence from the rest of the specification, which requires only that the regions be "distinct" from another. Like the general statements in *Safari*, the sole mention of "separate" is insufficient, in view of its absence from the rest of the specification, to exclude distinct, but partially overlapping first and second regions.

A careful read of the patent illustrates that "separate" regions can overlap. The patent does not teach a maximum read length; only that a reaction need not sequence "every base on the entire fragment." 6:44-48. Figure 1, for example, shows two reads of 25 base pairs using primers on two "different positions" in a template. Figure 1; 4:28-38. Both reads can come from the same strand, which can be between 50-150 base pairs. 4:16-24; 7:58-65. Thus, the patent could allow reads of more than 25 bases each, from primers of 10 base pairs, obtained from a strand 50

base pairs in length. In this case, the regions would overlap. Illumina's proposal would exclude this result.

Second, the use of a double-stranded template, where the first and second regions are located on either the same strand (embodiment 3) or complementary strands (embodiments 1-2), is a central feature of the "*invention*" as a whole:

> The first and second regions for sequence determination are *either on the same strand, or on complementary strands, of the double-stranded polynucleotide template* . . . .

5:51-58. While CGI has adopted this language verbatim, Illumina makes no mention of the template strands where the regions are located. This omission weighs against Illumina's proposal. CGI's more complete proposal should be adopted.

5. "different location"

CGI's Proposed Construction	Illumina's Proposed Construction
location of the second region that is distinct from the first region	a location distinct and separate from the location of hybridizing and reading from the first primer

The parties dispute whether the "different location" of the second sequencing run must merely be distinct, or distinct *and* separate, from the first region. For the reasons stated in the "first and second regions" section, CGI's construction should be adopted because it is faithful to the specification, which does not preclude overlap between the first and second region.

CONCLUSION

For these reasons, CGI's constructions should be adopted because they are firmly rooted in the intrinsic evidence and true to the intent behind the patent.

Dated: May 29, 2013

Respectfully submitted,

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PROOF OF SERVICE

I am an attorney, and on May 29, 2013, I caused a true and correct copy of **Complete Genomics, Inc.'s OPENING CLAIM CONSTRUCTION BRIEF [REDACTED]** to be served on the parties set forth below:

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I declare under penalty of perjury that the foregoing is true and correct.

Executed this 29th day of May 2013.

/s/ *Marisa Armanino Williams*
Marisa Armanino Williams